

United States Department of Agriculture  
Animal and Plant Health Inspection Service  
Plant Protection & Quarantine  
4700 River Road  
Riverdale, MD 20737

**Permit to Move Live Plant Pests, Noxious Weeds, and Soil**  
Interstate Movement  
**Regulated by 7 CFR 330**

This permit was generated electronically via the ePermits system

<b>PERMITTEE NAME:</b>	Christina Huben	<b>PERMIT NUMBER:</b>	P526P-18-03426
<b>ORGANIZATION:</b>	BioConsortia, Inc.	<b>APPLICATION NUMBER:</b>	P526-180827-015
<b>ADDRESS:</b>	1940 Research Park Drive Suite 200 Davis, CA 95618	<b>FACILITY NUMBER:</b>	3461
<b>MAILING ADDRESS:</b>	1940 Research Park Drive Suite 200 Davis, CA 95618	<b>HAND CARRY:</b>	No
<b>PHONE:</b>	530-564-5572	<b>DATE ISSUED:</b>	09/24/2018
<b>FAX:</b>		<b>EXPIRES:</b>	<b>09/24/2021</b>
<b>DESTINATION:</b>	BioConsortia LAB (FACILITY # 3461), 1940 Research Park Drive, Davis, CA 95618		
<b>RELEASE:</b>	No		

Under the conditions specified, this permit authorizes the following:

<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Archaea	Any	Research - Growth Chamber (lab included)	HI, MP, PR, VI	Originally Collected from HI, PR, and the U.S. Territories	
Bacteria	Any	Research - Growth Chamber (lab included)	HI, MP, PR, VI	Originally Collected from HI, PR, and the U.S. Territories	
Fungi	Any	Research - Growth Chamber (lab included)	HI, MP, PR, VI	Originally Collected from HI, PR, and the U.S. Territories	
Virus	Any	Research - Growth Chamber (lab included)	HI, MP, PR, VI	Originally Collected from HI, PR, and the U.S. Territories	

**PERMIT GUIDANCE**

1) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.

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Osmond Baron

DATE

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- 2) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to [http://www.aphis.usda.gov/import\\_export/animals/animal\\_import/animal\\_imports\\_an\\_products.shtml](http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_an_products.shtml)
- 3) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 4) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 5) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

### PERMIT CONDITIONS

USDA-APHIS issues this permit to Christina Huben with BioConsortia, Incorporated in Davis, CA (location of Organization). This permit authorizes the interstate movement of the listed regulated materials/organisms from the listed countries/states and/or territories.

1.
  - This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
  - The permit number or a copy of the permit must accompany the shipment.
  - You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
  - You are legally responsible for complying with all permit requirements and permit conditions.
  - If you violate any applicable laws associated with this permit, you may face substantial civil or criminal penalties. We may cancel all current permits and deny future permit applications.
  - Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

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2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or [pest.permits@aphis.usda.gov](mailto:pest.permits@aphis.usda.gov) within one business day of the event triggering a notification.

3. This permit does not authorize movement or use of plant pathogens listed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. If any organism listed as a Select Agent is identified from materials associated with this research, the permit holder is required to notify APHIS, Agriculture Select Agent Services (AgSAS) immediately by phone at 301-851-3300 option 3, and within seven (7) days submit APHIS/CDC Form 4A (Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory) to APHIS, AgSAS; 4700 River Rd, Unit 2, Riverdale, MD 20737 (see instructions at: [https://www.selectagents.gov/resources/APHIS-CDC\\_Form\\_4\\_Guidance\\_Document.pdf](https://www.selectagents.gov/resources/APHIS-CDC_Form_4_Guidance_Document.pdf)). Failure to comply with this requirement is a violation of the Agricultural Bioterrorism Protection Act of 2002. Plant pathogen select agents currently listed include: *Peronosclerospora philippinensis*

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(*Peronosclerospora sacchari*), *Conothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*), *Ralstonia solanacearum*, *Rathayibacter toxicus*, *Sclerophthora rayssiae*, *Synchytrium endobioticum*, and *Xanthomonas oryzae*.

4. All persons working with the listed regulated materials/organisms must be informed of these permit conditions. Anyone working with these materials/organisms must agree to and sign/initial these conditions before beginning work. These signed conditions do not need to be submitted to USDA/APHIS but must be readily accessible and made available to Federal and State regulators upon request.

Note: these conditions may be copied and stored electronically for electronic signature and initialing provided that the permit number, authorized materials/organisms and life stages, release locations if applicable, and authorization statement all appear on the document with the permit number. Signing these conditions only indicates that the person working under this permit has read them; the permit holder is the sole responsible party under this permit.

5. All persons working with the regulated material/organism must be trained on the importance of APHIS approved containment practices as described in the permit conditions and approved SOPs associated with the APHIS approved containment facility listed above.
6. APHIS authorizes the Chemical/Physical analysis procedures (including DNA/RNA), typically authorized under a separate PPQ 330 soil permit, only if the SOPs on file addresses this use.
7. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
8. Upon receipt, all packages must be opened within a Class II or III biosafety cabinet in the approved containment facility to prevent the potential dissemination of the package contents. All isolations and culture transfers must be made in the biosafety cabinet.
9.
  - Adequate protective clothing must be worn when working with soil and infected/infested samples so that movement of plant pests out of the facilities on hands, clothing, and shoes does not occur.
  - The laboratory floor must be uniform (i.e., no cracks/defects) and made of materials that can be cleaned. The floor must be maintained free of soil and infected/infested material.
  - Work benches must be uniform (i.e., no crack/defects) and made of materials that can be cleaned. When not working with the regulated material, the benches must be cleaned and maintained free of soil and infected/infested material.

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- Any sink/laboratory water that may contain live nematode life stages harbored by infested soil, infested growing media, and infected plant materials must be equipped with traps that allow collection of waste water. The waste water must be treated according to the devitalization and waste disposal condition in this permit before final disposal.
10. Upon receipt all samples potentially containing mobile arthropod life stages must be placed in a refrigerator for at least 4 hours prior to opening the package. Following this initial processing, living samples must be placed in sealed containers for subsequent diagnostic determinations.
11. Arthropod: (If included in samples)

Arthropod specimens that are either frozen, preserved in 70 percent alcohol, or preserved in another medium (e.g. fixed in glutaraldehyde) may be moved intra- and interstate without further permitting.


12. Plant and animal inoculations in the greenhouse, and/or field research of plant pests or biocontrol organisms are not authorized under this permit (separate permits are required for such activities).

The regulated materials/organisms listed in this permit are strictly for research in a controlled laboratory and growth chamber environment that includes use of soil as a growing medium.

13. Vector transmission is not permitted under this authorization.
14. If intending to retain an identified isolate that appears to be or is a plant pest or pathogen, the permit holder or authorized individual must notify APHIS-PPQ Pest Permit Staff within 10 working days of the confirmation that the organism is identified as (a) a species new to science, (b) an organism not known to occur in the United States, (c) a pest or pathogen managed by an APHIS program (program pest; [http://www.aphis.usda.gov/plant\\_health/plant\\_pest\\_info/index.shtml](http://www.aphis.usda.gov/plant_health/plant_pest_info/index.shtml)), (d) a pest or pathogen that is not widely prevalent in the State in which the containment facility is located ([http://www.aphis.usda.gov/plant\\_health/permits/organism/wpp/index.shtml](http://www.aphis.usda.gov/plant_health/permits/organism/wpp/index.shtml)), or (e) a Select Agent (refer to condition #3 above for the plant pathogen select agents currently listed). Include the permit number, the origin(s) and date(s) of receipt of the sample(s), and the identified organism. The notification must be sent to USDA/APHIS/PPQ/PCC, 4700 River Rd., Unit 133, Riverdale, MD 20737; or faxed to 301-734-8700; or emailed to [Pest.Permits@aphis.usda.gov](mailto:Pest.Permits@aphis.usda.gov) as Word, Excel or pdf document. Notifications must also be sent to the State Plant Health Director (SPHD) and State Plant Regulatory Official (SPRO) (of the State in which the containment facility is located) within 10 working days (see [http://www.aphis.usda.gov/services/report\\_pest\\_disease/report\\_pest\\_disease.shtml](http://www.aphis.usda.gov/services/report_pest_disease/report_pest_disease.shtml) and <http://www.nationalplantboard.org/member/index.html> for contact information).

The Permit holder must obtain a PPQ 526 Continued Curation permit (with the new intended use) to retain or work on the identified plant pest or pathogen isolated from materials received under

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this permit.

The permit holder must have a valid PPQ 526 permit to maintain biocontrol organisms isolated from imported soils, plant material, or other sources.

15. A separate continued curation PPQ 526 permit is required if the permit holder wishes to retain plant pathogens, plant pests, and biocontrol organisms isolated and identified from the regulated material for a new intended use.
16. Standard Operating Procedures (SOPs) must be filed with, and approved by, the APHIS PPQ Pest Permit Staff at: email: pest.permits@aphis.usda.gov; phone: 866-524-5421; fax: 301-734-8700; address: 4700 River Road, Unit 133, Riverdale, MD 20737. All contact information must be kept current and the SOPs must be dated. If requirements in the permit conditions are more restrictive than the SOPs, permit conditions take precedence. APHIS PPQ must approve any changes to the SOPs before implementation.

A list of all persons with access to the containment facility must be maintained and available upon request by Federal or State Regulatory Officials.

17. Modifications to the containment facility or any changes that affect the containment of the regulated materials/organisms must be approved by APHIS prior to making changes. Please contact the Pest Permit Staff (email: pest.permits@aphis.usda.gov; phone: 866-524-5421; address: 4700 River Rd., Unit 133, Riverdale, MD 20737; Fax: 301-734-8700).
18. DEVITALIZATION AND WASTE DISPOSAL


All regulated materials/organisms and all items coming in direct contact or exposed to the regulated materials/organisms must be sterilized/sanitized/decontaminated prior to removal from the authorized containment facility. This includes all items from shipping, culturing, care, and maintenance of these regulated materials/organisms. This requirement includes but is not necessarily limited to: packaging directly exposed to the regulated materials/organisms, substrates (culture media, soil, plant materials (food materials or host plants)), leftover/unused/unneeded live cultures, and dead specimens/cultures unless specified otherwise in the permit.

All waste materials must be treated by one of the follow methods prior to disposal:

Use any of the following, either alone or in combination: 1) autoclaved (see protocol below), 2) disposed of off-site by a facility holding a valid PPQ compliance agreement (organisms and/or contaminated waste must be stored in sealed containers prior to pick up by this company), 3) incinerated, 4) immersed in 5,250-6,000 PPM sodium hypochlorite solution (1 part fresh household bleach to 9 parts water) for at least 20 minutes, or 5) immersed in 70 percent alcohol for at least 30 minutes.

Treated waste will be double bagged prior to disposal.

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Other sterilization methods are only allowed with prior written agreement from the USDA/APHIS PPQ Pest Permit Staff.


Any equipment, supplies, tools, secondary shipping containers, packing materials (e.g, ice packs), etc. must be sterilized/sanitized/decontaminated prior to reuse, disposal, or removal from containment.

If using an autoclave the following protocol must be used:

- a. Waste must be autoclaved at 121 Celsius (250 Fahrenheit) for a minimum of 30 minutes at 15 psi.
  - b. Autoclave tape or other indicators must be placed on each load prior to treatment. The autoclave tape or other indicator on each container must be checked to verify color change before disposal.
  - c. The autoclave must be calibrated according to the manufacturer's instructions annually and a written record must be maintained.
  - d. Every 3 months, you must use a commercially available biological indicator kit that uses bacterial spores of *Geobacillus stearothermophilus* that are rendered unviable at 121 Celsius (250 Fahrenheit). You must follow the manufacturer's instructions. If any growth is observed, you must have the autoclave serviced and retested.
19. There is to be no further movement or distribution of the listed regulated materials/organisms within the United States and its territories unless the recipient holds, or is named as a responsible party on a valid PPQ526 permit for receipt of such materials/organisms.

**END OF PERMIT CONDITIONS**

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